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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/912,122	07/24/2001	Joshua Makower	TRNSV-015G	4515

7590 04/19/2006

MEDTRONIC VASCULAR, INC.
IP LEGAL DEPARTMENT
3576 UNOCAL PLACE
SANTA ROSA, CA 95403

EXAMINER

ISABELLA, DAVID J

ART UNIT	PAPER NUMBER
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3738

DATE MAILED: 04/19/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/912,122	MAKOWER ET AL.	
	Examiner	Art Unit	
	DAVID J. ISABELLA	3738	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
 - If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
 - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 20 January 2006.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 53-58 and 61-63 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 53-58 and 61-63 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

Response to Appeal Brief

Applicant's arguments directed to the rejections to the claims are well presented and, therefore, the finality of that action is withdrawn.

Status of the Claims

Claims 52-58,61-63 are pending for action.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claim 53 is rejected under 35 U.S.C. 102(e) as being anticipated by Lary et al [5800450].

Lary et al discloses a system [10] that is useable to guide the advancement of a guidewire [40] from a location within the lumen of a blood vessel to a location within or outside of the wall of that blood vessel, said system comprising: a elongate catheter body [12] that is advanceable into said blood vessel lumen, said catheter body having at least one lumen extending longitudinally therethrough; an opening formed in said catheter body; a tissue penetrating element [14] having a lumen, a tissue penetrating distal tip and a distal end opening, said tissue penetrating element being alternately

disposable in; a) a first position wherein the tissue penetrating element is substantially within the catheter body; and b) a second position wherein the tissue penetrating element assumes a predetermined curved configuration and extends out of the opening so as to penetrate a wall of the blood vessel adjacent to the blood vessel lumen in which the catheter is positioned wherein the guidewire is advanceable through the lumen of the tissue penetrating element while the tissue penetrating element is in the second position.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 52-58,61-63 are rejected under 35 U.S.C. 103(a) as being unpatentable over Makower [WO 93/15664] in view of Murphy Chutorian [5891133].

Makower discloses a system [10] that is useable to guide the advancement of a guidewire [20] from a location within the lumen of a blood vessel to a location within or outside of the wall of that blood vessel, said system comprising: a elongate catheter body [30] that is advanceable into said blood vessel lumen, said catheter body having at least one lumen extending longitudinally therethrough; an opening [108] formed in said catheter body; a tissue penetrating element [20] having a lumen, a tissue penetrating

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distal tip and a distal end opening, said tissue penetrating element being alternately disposable in; a) a first position wherein the tissue penetrating element is substantially within the catheter body; and b) a second position wherein the tissue penetrating element assumes a predetermined curved configuration and extends out of the opening so as to penetrate a wall of the blood vessel adjacent to the blood vessel lumen in which the catheter is positioned.

Makower does not clearly disclose a guidewire that is advanceable through the lumen of the tissue penetrating element while the tissue penetrating element is in the second position however the laser element may be replaced with other elements such as a separate stylet or hollow needle (see page 14, 3rd paragraph). Murphy-Chutorian teaches the combination of a fiber optic/guidewire bundle that is used for laser assisted TMR procedures. To replace the fiber of Makower with the fiber/guidewire bundle of Murphy-Chutorian to obtain better control of the placement of the fiber with respect to the predetermined tissue site would have been obvious to one with ordinary skill in the art at the time of the invention thereof. Makower as modified would yield a system that meets the claimed limitations.

Claim 54, see anchoring member [locking member 16] of Makower

Claim 55, see page 12, 1st paragraph of Makower.

Claims 56,57 are rejected under 35 U.S.C. 103(a) as being unpatentable over Makower [WO 93/15664]) in view of Abele (6010480).

Examiner has applied Abele et al as a secondary teaching for increasing the frictional surface of a balloon catheter for increasing the engaging forces of the balloon to an adjacent luminal structure. It would have been obvious to one with ordinary skill in the art to provide the outer surface of the balloon with frictional components to increase the engaging forces of the outer surface of the balloon to adjacent luminal structures.

Claims 61-63 are rejected under 35 U.S.C. 103(a) as being unpatentable over Makower [WO 93/15664] in view of Edwards et al [5366490] and Shturman (5331947).

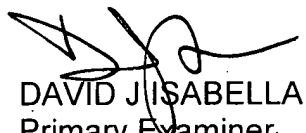
While it is not clear how Makower combines the ultrasound imaging in combination with the system [10], an imaging device comprising an anchoring member (30,32) being deployable when the catheter body is inserted into an anatomical lumen such that a surface of the balloon anchoring member will engage a wall of the anatomical lumen thereby preventing at least a portion of the catheter body from undergoing substantial movement within the anatomical lumen is taught by Edwards et al.. Shturman teaches placement of the ultrasound transducer internal to the lumen for imaging the same. It is not inherent in Makower to place the imaging device internally of the lumen along with the combination of a balloon anchor/imaging means, so that the surgeon can precisely place and anchor the probe at the predetermined/selected location in vivo would have been obvious to one with ordinary skill in the art at the time of the invention thereof. Precise location and anchoring the probe to that location offers the surgeon better means for obtaining clear imaging resolution of the selected location.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to DAVID J. ISABELLA whose telephone number is 571-272-4749. The examiner can normally be reached on MONDAY-FRIDAY.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, CORRINE MCDERMOTT can be reached on 571-272-4754. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).


DAVID J. ISABELLA
Primary Examiner
Art Unit 3738

DJI
4/13/2006